

CHAPTER 61-04-11
ADMINISTRATION OF MEDICATIONS AND IMMUNIZATIONS

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61-04-11-01. Definitions. For purposes of this chapter:

1. "Authorized pharmacist" means a pharmacist who has successfully completed a board-approved course of study pertaining to the injectable administration of drugs and maintains continuing competency according to rules adopted by the board.
2. "Certificate of authority" means documentation provided by the board to an authorized pharmacist, which must be displayed in the pharmacy at which the pharmacist is practicing.
3. "Written protocol" means a standing medical order between a physician or nurse practitioner and an authorized pharmacist which contains information required by board rules.

History: Effective May 1, 2002.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10, 43-15-31.5

61-04-11-02. Qualifications established to obtain certificate of authority. A pharmacist must possess the following qualifications in order to obtain a certificate of authority from the board:

1. Obtain and maintain a license to practice pharmacy issued by the North Dakota state board of pharmacy;
2. Successfully complete a board-approved twenty-hour course of study and examination pertaining to the administration of medications by injection, which includes the current guidelines and recommendations of the centers for disease control and prevention. The course of study must be administered by an approved provider and consist of study material and hands-on training in techniques for administering injections. The course must require testing and completion with a passing score. The provider of the course of study shall provide successful participants with a certificate of completion. A copy of said

certificate must be mailed to the state board of pharmacy offices and placed in the pharmacist's permanent file. The course of study must include, at a minimum:

- a. Basic immunology, including the human immune response;
 - b. The mechanism of immunity, adverse effects, dose, and administration schedule of available vaccines;
 - c. Vaccine-preventable diseases;
 - d. Current immunization guidelines and recommendations of the centers for disease control and prevention;
 - e. Vaccine storage and management;
 - f. Management of adverse events due to the administration of medications by injection, including identification, appropriate response, documentation, and reporting;
 - g. Patient education on the need for immunizations;
 - h. Informed consent;
 - i. Physiology and techniques for subcutaneous, intradermal, and intramuscular injection; and
 - j. Recordkeeping requirements established by law and rules or established standards of care;
3. Obtain and maintain current certification in cardiopulmonary resuscitation or basic cardiac life support;
 4. Complete an application process adopted by the board and provide required documentation; and
 5. Maintain continuing competency to retain the certificate of authority. A minimum of six hours of the thirty-hour requirement for continuing education, every two years, must be dedicated to this area of practice.

History: Effective May 1, 2002.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10, 43-15-31.5

61-04-11-03. Procedures to obtain certificate of authority. An authorized pharmacist shall provide the board with a copy of a certificate of completion from a board-approved course, a copy of current certification in cardiopulmonary resuscitation or basic cardiac life support, and other information required on a form supplied by the board. If requirements are met, the board shall issue a certificate

of authority that shall be valid for two years. In order to renew the certificate, the pharmacist shall submit evidence of six hours of continuing education dedicated to this area of practice.

History: Effective May 1, 2002.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10, 43-15-31.5

61-04-11-04. Requirements of physician or nurse practitioner order for a pharmacist to administer injections. The order must be written, received electronically or if received orally be reduced to writing, and must contain at a minimum the:

1. Identity of the physician or nurse practitioner issuing the order;
2. Identity of the patient to receive the injection;
3. Identity of the medication or vaccine, and dose, to be administered; and
4. Date of the original order and the dates or schedule, if any, of each subsequent administration.

History: Effective May 1, 2002; amended effective January 1, 2005.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10, 43-15-31.5

61-04-11-05. Requirements of written protocol. A physician or nurse practitioner may prepare a written protocol governing the administration of medications by injection with an authorized pharmacist for a specific period of time or purpose. The written protocol may be valid for a time period not to exceed two years, subject to earlier withdrawal by the physician or nurse practitioner. The protocol must contain the:

1. Identity of the participating physician or nurse practitioner and the pharmacist;
2. Identity of the immunization or vaccination which may be administered;
3. Identity of the patient or groups of patients to receive the authorized immunization or vaccination;
4. Identity of the authorized routes and sites of administration allowed;
5. Identity of the course of action the pharmacist shall follow in the case of reactions following administration;
6. Identity of the location at which the pharmacist may administer the authorized immunization or vaccination; and

7. Recordkeeping requirements and procedures for notification of administration.

History: Effective May 1, 2002.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10, 43-15-31.5

61-04-11-06. Requirements of records and notifications. A pharmacist administering by injection shall meet the following recordkeeping and notification requirements:

1. Notification of administration must be made to the ordering physician or nurse practitioner and other authorities as required by law and rule.
 - a. When administration has occurred pursuant to an order, the pharmacist shall notify the ordering physician or nurse practitioner within forty-eight hours of the identity of the patient, identity of the medication or vaccine administered, route of administration site of the administration, dose administered, and date of administration and the disposition of any adverse events or reactions experienced by the patient.
 - b. When administration has occurred pursuant to a written protocol, the pharmacist shall notify the participating physician or nurse practitioner within fourteen days of the identity of the patient, identity of the medication or vaccine administered, site of the administration, dose administered, and date of administration and the disposition of any adverse events or reactions experienced by the patient.
 - c. In the case of immunizations and vaccinations, the pharmacist shall also provide notification to the physician or nurse practitioner of the manufacturer and lot number of the product administered.
2. Every record, including notification, which is required to be made under this section, must be kept by the administering pharmacist and by the pharmacy when in legal possession of the drugs administered for at least two years from the date of administration. Records of administration must contain all information required in subsection 1, plus the name of the ordering physician or nurse practitioner. Records of administration by order must be by patient name and, in the case of administration by written protocol, records may be maintained in roster form.

History: Effective May 1, 2002.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10, 43-15-31.5

61-04-11-07. Location of administration by injection. Pharmacists may administer medications by injection within a licensed North Dakota pharmacy or at a location within North Dakota specifically identified in a written protocol. The location in the pharmacy must:

1. Ensure privacy;
2. Be maintained to promote an aseptic environment;
3. Have adequate telecommunications devices to summon aid and communicate emergency situations; and
4. Have adequate equipment and supplies to respond to adverse events and emergency situations.

History: Effective May 1, 2002.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10, 43-15-31.5

61-04-11-08. Policy and procedural manual. The pharmacy shall maintain a current policy and procedural manual related to the administration of medications by injection.

History: Effective May 1, 2002.

General Authority: NDCC 43-15-10

Law Implemented: NDCC 43-15-10, 43-15-31.5